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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/797,348

03/10/2004

Lyle Brostrom

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06/01/2006

Pharmacia Corporation
Corporate Patent Department
P.O. Box 1027
Chesterfield, MO 63006

EXAMINER

VALENROD, YEVGENY

ART UNIT

PAPER NUMBER

1621

DATE MAILED: 06/01/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/797,348

Applicant(s)

BROSTROM, LYLE

Examiner

Yevgeny Valenrod

Art Unit

1621

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-4 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☐ Claim(s) 1-4 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 17 June 2004 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. ____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. ____. |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>6-14-04</u> . | 6) <input type="checkbox"/> Other: ____. |

DETAILED ACTION

Rejections 35 USC 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 3 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. In claim 3 the applicant refers to "...a condition wherein pathologically high production forms a part in a subject...". Applicant fails to point out what exactly is being produced and it is unclear what is meant by phrase "forms a part in a subject".

Claims 1-4 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Each claim refers to an X-ray diffractogram. According to MPEP §2173.05(s) "Reference to Figures or Tables Where possible, claims are to be complete in themselves. Incorporation by reference to a specific figure or table "is permitted only in exceptional circumstances where there is no practical way to define the invention in words and where it is more concise to incorporate by reference than duplicating a drawing or table into the claim. Incorporation by reference is a necessity doctrine, not for applicant's convenience." *Ex parte Fressola*, 27 USPQ2d 1608, 1609 (Bd. Pat. App. & Inter. 1993) (citations omitted)." The Examiner suggests incorporation of the desired figure into the claim.

Rejections 35 USC 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-4 are rejected under 35 U.S.C. 103(a) as being unpatentable over Webber et al. (US 6,586,474).

The instant application claims a crystalline form of S-[2-[(1-Iminoethyl)amino]ethyl]-2-methyl-L-cysteine maleate with specific listed characteristics. It also claims the pharmaceutical composition comprising the said compound, a method of treating a condition, which includes for example Parkinson's disease and a method of decreasing nitric oxide production.

Prior art

Webber et al. teach S-[2-[(1-Iminoethyl)amino]ethyl]-2-methyl-L-cysteine maleate (see column 13, formula 1, when R1, R3-R7 and R9-R12 are H; R8 is OH; R2 and R13 are Me. Column 15, line 54 lists maleate as one of the acceptable salts). Webber et al. further teach using the said compound to treat conditions including Parkinson's disease (column 6, line 7) and inhibiting Nitrous Oxide production (Column 7, line 5). They also teach pharmaceutical compositions and pharmaceutically acceptable carrier (column 25, lines 29-40).

Ascertaining the difference between prior art and instant claims

Webber et al. teach S-[2-[(1-Iminoethyl)amino]ethyl]-2-methyl-L-cysteine maleate and its use in treating diseases. Although Webber et al. teach the compound, they do not teach the exact crystalline form as claimed by the applicant.

Obviousness

The crystalline structure claimed by the applicant displays no unexpected results over the prior art. The claimed compound carries same expectancy of success in treating a condition independent of what form the compound is in. One of ordinary skill in the art would therefore be motivated to use any form of the compound to achieve the desired effect.

With regard to treating a condition using the claimed compound, Webber et al. teaches a method of using S-[2-[(1-Iminoethyl)amino]ethyl]-2-methyl-L-cysteine maleate to treat conditions which include the conditions listed in the instant application, for example Parkinson's disease. Since treating Parkinson's disease with the said compound is known in the art and there are no unexpected results pertaining to the specific crystalline form of the compound, one of ordinary skill in the art would find it obvious to use any form of the said compound, including the one claimed by the applicant, for treatment of Parkinson's.

Applicant has provided evidence in this file showing that the invention was owned by, or subject to an obligation of assignment to, the same entity as assignee at the time this invention was made, or was subject to a joint research agreement at the time this

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invention was made. However, reference US 6,586,474 additionally qualifies as prior art under another subsection of 35 U.S.C. 102, and therefore, is not disqualified as prior art under 35 U.S.C. 103(c).

Applicant may overcome the applied art either by a showing under 37 CFR 1.132 that the invention disclosed therein was derived from the invention of this application, and is therefore, not the invention "by another," or by antedating the applied art under 37 CFR 1.131.

Conclusion

- Claims 1-4 are pending in the application;
- Claims 1-4 are rejected under 35 USC 112;
- Claims 1-4 are rejected under 35 USC 103.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Yevgeny Valenrod whose telephone number is 571-272-9049. The examiner can normally be reached on 8:30am-5:00pm M-F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman Page can be reached on 571-272-0602. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

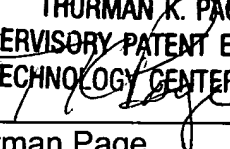
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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.



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